REMARKS

Claims 1-10 are pending. No amendments are proposed at this time; rather, reconsideration of the application is requested in view of the remarks which follow.

Claims 1-10 stand rejected under 35 USC §102(b) over Grimmett et al. (WO 95/28148).

The rejection is traversed. The cited reference does not teach or suggest the cored tablets or methods of the present invention.

For instance, the present invention relates to a cored tablet comprising: i) a core layer which contains clavulanate; and ii) an outer layer surrounding the core layer which contains amoxicillin. According to the present invention, clavulanate is prevented from contacting the amoxicillin, and the amoxicillin-containing outer layer suitably blocks moisture from the outside, thereby stabilizing the clavulanate in the core layer. As a result, the formulation of the present invention has an improved pharmaceutical effect.

In contrast, Grimmett et al. discloses a tablet formulation comprising: i) a core which includes a first active material; ii) a release retarding coating; and iii) a casing layer which includes a second active material. Specifically, attention is directed to Grimmett et al. at page 1, lines 36-38, where it is described that amoxicillin should be contained in both the core and the casing layer, and clavulanate optionally can be contained in either the core or the casing layer, or both.

Furthermore, in determining the sufficiency of any given prior art reference, due consideration and weight must be given to whether or not the prior art exemplifies the claimed invention by working examples. In this case, Example 1 of Grimmett et al. describes that amoxicillin was mixed with clavulanate, compacted, and then applied to both the core and the casing layer of Tablets 1 and 2 (see, pages 7-10 of Grimmett et al.). In contrast, for the cored tablet of the present invention, clavulanate is contained in the core layer and amoxicillin is contained in the outer layer surrounding core layer.

Thus, the present invention is greatly different from Grimmett et al. in terms of the constitution of the tablet.

For at least the foregoing reasons, Grimmett et al. is insufficient to sustain the §102 rejection. Accordingly, the rejection should be withdrawn. See, for instance, *In re Marshall*, 198 USPQ at 346 ("[r]ejections under 35 U.S.C. 102 are proper only when the claimed subject matter is identically disclosed or described in the prior art."). Reconsideration and withdrawal of the §102 rejection are requested.

Claims 1-10 stand rejected under 35 USC §103(a) over Ebbers et al. (WO 95/20946) in view of Faour et al. (USP 6,004,582).

The rejection is traversed. Even in combination, the cited references fail to teach or suggest the present invention.

For instance, Ebbers et al. allegedly discloses a tablet formulation comprising: i) a first layer which includes amoxicillin and/or clavulanate; and ii) a second layer which includes amoxicillin and/or clavulanate.

However, Ebbers et al. discloses only a simple bilayered tablet (see, e.g., Figures 1A to 1E of Ebbers et al.), and does not teach or suggest the "cored tablet" of the present invention comprising a core layer and an outer layer surrounding the core layer. The "cored tablet" of the present invention separates clavulanate from amoxicillin by containing clavulanate in the core and amoxicillin in the outer layer, respectively, thereby preventing an increase in moisture caused by mixing clavulanate with amoxicillin as well as input of additional moisture from the outside, and minimizing the moisture content of the core layer containing clavulanate. Indeed, Ebbers et al. did not even recognize the necessity for a "cored tablet", and so the tablet formulation of Ebbers et al. is merely a controlled-release formulation of amoxicillin.

Faour et al. cannot remedy the deficiencies of Ebbers et al. Faour et al. discloses a multi-layered osmotic device comprising: i) a core which contains a first active agent and an osmotic agent for controlled release of a drug; ii) a semipermeable membrane surrounding the core; iii) a water soluble polymer coat; and iv) an external coat which contains a second active agent.

Significantly, the core disclosed in Faour et al. is separated from the external coat by iii) the water soluble polymer coat comprising poly(vinylpyrrolidone)-(vinyl acetate) copolymer. In contrast, such water soluble polymer is not a feature of the cored tablet of the present invention, and the polymer has no relation to the present invention. As that reference is understood, the object of the multi-layered osmotic device of Faour et al. can never be accomplished without the above essential feature iii). Also, Faour et al. merely relates to a controlled-release formulation of a drug, and does not even recognize the disadvantages of the mixed formulation of amoxicillin and clavulanate.

Moreover, the stability test results of clavulanate and amoxicillin in the present application showed that the cored tablets of Examples 1 to 3 contained clavulanate more than about 96% after storage of 4 months, while the tablets of Comparative Examples 1 to 3 contained clavulanate of much less content of about 77%. In addition, the cored tablets of Examples 1 to 3 contained almost the same content of amoxicillin, but those of Comparative Examples 1 to 3 contained much less content of amoxicillin. Therefore, it is clear that the cored tablets of the present invention have much higher stability than the prior art tablets. These superior and unexpected results further rebut any *prima facie* case of obviousness which may be contended.

In view of the foregoing, Ebbers et al. in combination with Faour et al. do not lead to the present invention, and it is respectfully submitted that the present invention is not rendered obvious by these two cited references.

Accordingly, the §103 rejection is properly withdrawn. See, e.g., Section 2143.03 of the Manual of Patent Examining Procedure ("To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art.").

Additionally, it is well-known that to establish a *prima facie* case of obviousness, three basic criteria must be met: (1) there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings; (2) there must be a reasonable expectation of success; and (3) the prior art reference(s) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). See MPEP § 2143.

There is no suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the cited references to arrive at the claimed invention, nor is there a reasonable expectation of success. The art cited, even in combination, is deficient and cannot sustain the rejections. Reconsideration and withdrawal of the §103 rejection are requested.

Applicant believes the pending application is in condition for immediate allowance, which action is earnestly solicited.

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